# Fresenius Medical Care



DEC 3 0 2011

Fresenius Medical Care South Asia Pacific Pty Ltd

Fresenius Medical Care
South Asia Pacific Pty Ltd
ACN 128 754 218
Level 17, 61 Lavender Street
Milsons Point, NSW 2061
Australia
Tel: +61 (02) 9466 8000
Fax: +61 (02) 9929 5595

## 510(k) Summary

**Submitter Information:**

Fresenius Medical Care South Asia Pacific Pty Ltd
Level 17, 61 Lavender Street
Milsons Point NSW 2061
AUSTRALIA

**Contact Person:**

Mr Ram Kamath
Quality, Regulatory Affairs & Management Systems Manager - South Asia Pacific
Fresenius Medical Care South Asia Pacific Pty Ltd
T: +61 2 9466-8023
F: +61 2 9466-8073
e: ram.kamath@fmc-asia.com

**Manufacturer:**

Fresenius Medical Care South Asia Pacific Pty Ltd
Level 17, 61 Lavender Street
Milsons Point NSW 2061
AUSTRALIA

**Device Information:**

| | |
|---|---|
| Trade/Proprietary Name: | Fresenius Medical Treatment Chair T688 Series |
| Common/Usual Name: | Medical Treatment Chair |
| Classification Name: | Chair, Electric, Positioning<br>Chair, Dialysis, Powered Without Scales |

**Legally Marketed Predicate Device:**

Fresenius Medical Treatment Chair - T600 Series

**Device Description:**

T688 series chair is used to aid medical procedures such as renal dialysis, blood collection and chemotherapy and is called as Medical Treatment Chair.

T688 series is *electric-powered* treatment chair with the following features:

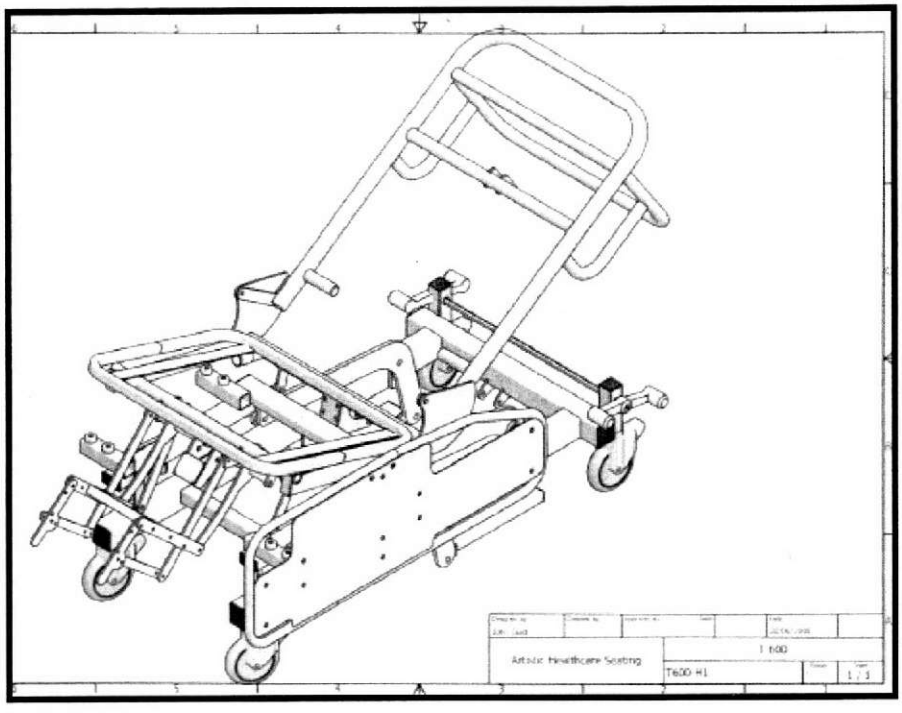
- Power-operated seat and leg rest and back rest reclines, with options offering one-touch memorized positions
- Swing Out Side/Arms
- Adjustable head/neck rest
- Adjustable height
- CPR support posts, gas spring assisted back rest and accessories.
- Fold-down trays
- Four individually locking castors
- Heavy duty washable vinyl
- Removable upholstery
- The chair will recline to Trendelenburg position
- Suitable for side transfer of patients
- No timber included in the frame
- Battery back-up-24V rechargeable
- 2 Actuators & 1 Column
- Compact Design
- Lighter weight
- Reduced components

The device is classified as:

- Class II (FKS, INO) – electric-powered version.

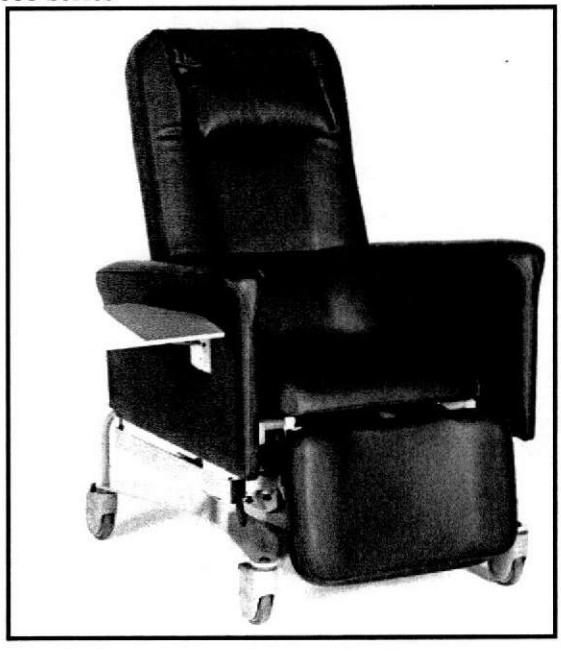
Specific ancillary devices and accessories are not listed here due to the wide variety of procedures in which the chair is used.

The following engineering drawing shows the final assembly for the T688 frame:



The configuration of the chair is shown in the photograph below:

**T688 Series**



| MODEL | Length Upright (mm) | Length Tren/CPR (mm) | Overall Width (mm) | Seat Width (mm) | Weight Capacity (kgs) | Seat Height to Floor (mm) | Seat Height to Footstool (mm) | Backrest Length (mm) |
|---|---|---|---|---|---|---|---|---|
| T688 Series | 930 | 1800 | 730 | 510 | 200 | 590 | n/a | 800 |

**Intended Use:**

The Medical Treatment Chair, T688 series is intended for use in medical procedures such as the administration of renal dialysis to, and collecting blood from, patients in hospital departments or home use, under the supervision of trained medical staff. The Medical Treatment Chair is also intended for use in day surgery and nursing homes. T688 chair is designed so that the occupant is accommodated in a seated position with the hips moved back so that the occupant's back is against the back rest and the legs outstretched and supported by the seat and leg rests.

T688 series chair is also used to position patients for easy access by healthcare professionals. The chair is designed so that the occupant is accommodated in a seated position with the hips moved back so that the occupant's back is against the back rest and the legs outstretched and supported by the seat and leg rests.

This chair is intended to be used by patients with a weight not exceeding:

- 200kg (T688 series)

**Substantial Equivalence:**

The Fresenius Medical Treatment Chair, T688 series and the predicate device (Fresenius Medical Treatment Chair, T600) are substantially equivalent and are similar in characteristics such as:

- Intended Use
- Basic construction
- Principles of operation
- Electrical and mechanical characteristics
- General safety and EMC compliance

However, the T688 series chair is an improved design with advance features when compared to T600 series. T688 is lighter in weight, compact design with central column lift, reduced number of components for easy repairs and maintenance, removable upholstery for easy cleaning, swing out side arms for patient side transfer and adjustable height. Compared to T600, the main difference is that T688 has a central column lift, which is a substantial variation to the design resulting in smaller foot print.

**Performance Standards:**

Although no performance standards or special controls have been developed under Section 514 of the FDC Act for Medical Treatment Chairs, Fresenius Medical Care South Asia Pacific Pty Ltd has chosen to test the Fresenius Medical Treatment Chair T688 series against self imposed load and repeatability test requirements. Representative samples for the device underwent load and repeatability testing to verify functional and performance characteristics.

**Biocompatibility:**

Materials used on the Fresenius Medical Treatment Chair T688 that may come into contact with patients are biocompatible. The material was evaluated in accordance with guidelines of ISO 10993: Biological Evaluation of Medical Devices, Part 1: Evaluation and testing within a risk management process.

**Electromagnetic Compatibility and Electrical Safety:**

The Fresenius Medical Treatment Chair T688 series meets the applicable requirements of IEC 60601-1 General Safety and IEC 60601-1-2 EMC.

**Cited Standards:**

| CRITICAL AREA | STANDARD |
|---|---|
| **Quality System standards** | ISO 13485:2003 (Medical devices -- Quality management systems -- Requirements for regulatory purposes) |
| **Risk Analysis standards** | ISO 14971:2009 (Medical devices -- Application of risk management to medical devices) |
| **Design Control** | |
| **Flame retardant** | California 117 sD p2 (Requirements, Test Procedure and Apparatus for Testing the Flame Retardance of Resilient Filling Materials Used in Upholstered Furniture)<br><br>AS/NZS4088.1:1996 (Specification for burning behaviour of upholstered furniture - Upholstery materials for domestic furniture - Smouldering ignitability)<br><br>AS 1530.3-1999 (Methods for fire tests on building materials, components and structures - Simultaneous determination of ignitability, flame propagation, heat release and smoke release) |
| **Frame loading** | AS 4688.2:2000 (Furniture – Fixed height chairs. Part 3: Determination of stability – Upright chairs, s8, s7.1) |
| **Electrical** | Whole Chair:<br>• IEC60601-1<br>• IEC60601-1-2 |
| **Biocompatibility** | ISO 10993 -1:2008 (Safety Machinery. Evaluation of the emission of airborne hazardous substances. Selection of test methods.) |
| **Castors and brakes** | EN 12526 - 12533 Castors and wheels. Hospital bed castors. |
| **Labelling** | BS EN 1041:2008 Information supplied by the manufacturer of medical devices<br><br>BS EN 980:2008 Symbols for use in the labelling of medical devices |
| **Clinical** | AS ISO 14155-1: 2004 Clinical investigation of medical devices for human subjects - General requirements<br><br>AS ISO 14155-2: 2004 Clinical investigation of medical devices for human subjects - Clinical investigation plans |

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Room –WO66-G609
Silver Spring, MD 20993-0002

Fresenius Medical Care South Asia Pacific Pty Ltd.
% Mr. Ram Kamath
Level 17, 61 Lavender Street
Milsons Point NSW 2061
Australia

DEC 30 2011

Re: K112944
Trade/Device Name: Medical Treatment Chairs – T688 Series
Regulation Number: 21 CFR 890.3110
Regulation Name: Electric positioning chair
Regulatory Class: Class II
Product Code: INO, FKS
Dated: September 26, 2011
Received: October 4, 2011

Dear Mr. Kamath:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you; however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set

forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please go to http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOffices/ucm115809.htm for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

Mark N. Melkerson
Director
Division of Surgical, Orthopedic
And Restorative Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

# Indications for Use Form

## Indications for Use

510(k) Number (if known): K112944

Device Name: Medical Treatment Chairs – T688 Series

Indications for Use:

The Medical Treatment Chair, T688 Series is intended for use in medical procedures such as the administration of renal dialysis to, and collecting blood from, patients in hospital departments or home use, under the supervision of trained medical staff. The Medical Treatment Chair is also intended for use in day surgery and nursing homes. T688 chair is designed so that the occupant is accommodated in a seated position with the hips moved back so that the occupant's back is against the back rest and the legs outstretched and supported by the seat and leg rests.

T688 chair is also used to position patients for easy access by healthcare professionals. The chair is designed so that the occupant is accommodated in a seated position with the hips moved back so that the occupant's back is against the back rest and the legs outstretched and supported by the seat and leg rests.

This chair is intended to be used by patients with a weight not exceeding:

- 200kg (T688 series)

Prescription Use _____ (Part 21 CFR 801 Subpart D)

AND/OR

Over-The-Counter Use X (21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE OF NEEDED)

---

Concurrence of CDRH, Office of Device Evaluation (ODE)

(Division Sign-Off)
Division of Surgical, Orthopedic,
and Restorative Devices

510(k) Number K112944